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SAFETY AND EFFICACY FOR NEW TECHNIQUES AND IMAGING USING NEW EQUIPMENT TO SUPPORT EUROPEAN LEGISLATION: AN EU COORDINATION ACTION

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The past two decades have witnessed a technologically driven revolution in radiology. At the centre of these developments has been the use of computing. These developments have also been driven by the introduction of new detector and imaging devices in radiology and nuclear medicine, as well as the widespread application of computing techniques to enhance and extract information within the images acquired. Further advances have been introduced into digital practice. These technological developments, however, have not been matched by justification and optimisation studies to ensure that these new imaging devices and techniques are as effective as they might be, or performed at the lowest possible dose. The work programme of the SENTINEL Coordination Action was subdivided into eight work packages: functional performance and standards; efficacy and safety in digital radiology, dentistry and nuclear medicine, cardiology, interventional radiology, population screening/sensitive groups; justification, ethics and efficacy; good practice guidance and training; and project management. The intention of the work programme was to underwrite the safety, efficacy and ethical aspects of digital practice as well as to protect and add value to the equipment used in radiology.

INTRODUCTION

The past two decades witnessed a technologically driven revolution in radiology. At the centre of these developments has been the use of computing in diagnostic imaging, which began with computer tomography (CT). These developments have also been driven by the introduction of new detectors and imaging devices in radiology and nuclear medicine as well as the widespread application of computing techniques to enhance and extract information within the images acquired. These technological developments, however, have not been matched by justification and optimisation studies to ensure that these new imaging devices and techniques are as effective as they might be, or performed at the lowest possible dose.

The SENTINEL Coordination Action has dealt with radiation protection, safety and related issues that arise from these developments in radiology. It covered over 90% of patient examinations, 60% of the collective dose from medical sources and ~50% of the collective dose from man-made sources. In practice, it dealt with almost all radiological digital imaging other than CT examinations.

The Coordination Action spanned the following:

- Functional and objective equipment performance and international standards,
- Dosimetry, constancy testing and quality assurance (QA),
- Justification, ethics and efficacy,
- Guidelines, good practice and
- Training materials.

Its intention was to underwrite the safety, efficacy and ethical aspects of clinical practice, while protecting and adding value to the products and of the associated knowledge-based equipment, devices, information technology (IT) and services industries in Europe.

A series of studies was undertaken on the justification and optimisation of new and emerging imaging techniques. These studies concentrated on examinations that were associated with high individual doses, frequently performed or apply to sensitive groups. The main objectives of SENTINEL were the following:

- For digital imaging and nuclear medicine, to establish both physical and clinical image quality criteria and link the two.
- Perform a series of dosimetry studies (on both patients and staff).
- Develop good practice guidelines for radiation protection, and training material.

The work programme of SENTINEL was subdivided into eight work packages (WP). These were: functional performance and standards; efficacy and safety in digital radiology, dentistry and nuclear medicine, cardiology, interventional radiology (IR), population screening/sensitive groups; justification, ethics and efficacy; good practice guidance and training; and project management. The various partners involved

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in the coordination action are presented in Table 1. The results obtained in the coordination action were presented during a final workshop held in Delft, 18–20 April 2007. The proceedings of the SENTINEL workshop are published in a special issue of Radiation Protection Dosimetry[1].

WP1: FUNCTIONAL PERFORMANCE AND STANDARDS

The objectives of this WP were to ensure that surveys within this area were conducted according to standards appropriate to the new ethical sensitivity and legislation. It also ensures that the standards defined for the performance of equipment based on new technology were consistent (1) with justification and optimisation and (2), between end users, regulators and industry. Standards needed to be defined for equipment performance appropriate to the new technology and to European user needs. In addition, these standards needed to be adopted by standards bodies and an information base for European industry had to be established.

Table 1. Organisations involved in the Coordination Action SENTINEL.

Organisation name	Country code
QARC, Newcastle, UK	UK
Haughton Institute, Dublin, Ireland	IR
Krankenhaus der Barmherzigen Brueder, Trier, Germany	D
Azienda Ospedaliera S. Maria Della Misericordia, Italy	I
Complutense University, Madrid, Spain	ES
Katholieke Universiteit, Leuven, Belgium	BE
Innsbruck Medical University, Department of Radiology, Austria	AU
Radiation Protection Department, Ministry of Health, Luxembourg	LU
STUK—Radiation and Nuclear Safety Authority, Finland	FIN
Delft University of Technology, The Netherlands	NL
National and Kapodistrian University of Athens, Greece	GR
Nofer Institute of Occupational Medicine, Radiation Protection Department, Lodz, Poland	PO
Biomedical Research Foundation, Nicosia, Cyprus	CY
MEDICONTROL, Vrbove, Slovenia	SK
Tartu Uelikool, Estonia	EE
Institute of Occupational Safety, Slovenia	SI
Ankara University, Faculty of Engineering, Turkey	TR
Physics Department, University of Pisa, Italy	I
National Centre of Radiobiology and Radiation Protection, Sofia, Bulgaria	BG
National Research Institute for Radiobiology and Radiohygiene, Budapest, Hungary	HU
NHS Lanarkshire Health Board, Scotland	UK
Institute of Public Health, Bucharest, Romenia	RO

The WP on functional performance and standards consisted of two major parts, i.e. standardisation requirements for new imaging techniques, and that on inventory, of assessment methodology and protocols.

A review of existing International Electrotechnical Commission (IEC) standards was undertaken prior to arranging the consensus meeting with IEC and representatives from industry. An IEC category D liaison between IEC and SENTINEL was established. A consensus meeting between IEC and SENTINEL representatives was arranged and took place in Delft, The Netherlands on October 4, 2006. The meeting was convened at the invitation of the IEC TC 62B committee. It was recognised that

- The existence of Digital Imaging and Communications in Medicine (DICOM) header was very important for image quality/patient dosimetry.
- Industry and end-users were parties of the same enterprise but functioned without much contact.
- Collaboration was needed and there was a need to identify issues that would be worth looking at in the future[2].

The second part of the WP dealt with surveying the inventory of equipment and equipment standards, agreeing on a basic toolkit of image quality and user performance assessment in fluoroscopy, organising a trial of image quality and physical measurements, performing a collation and analysis of equipment performance standards and, finally, arriving at a general protocol of equipment performance assessment/measurement. In addition, a theoretical study was performed on the link between user evaluation and physical measurement. The organisation, performance and the results of the trial with the SENTINEL toolkit were presented during the workshop[3].

The main conclusions were that only one participant was able to perform the monitor test using MoniQA. This is due to the fact that assistance is apparently required from the suppliers of the X-ray systems. This problem needs to be solved to apply MoniQA in practice. The Medical Physics and Bioengineering (MPBE) protocol developed by partner 2 for conventional fluoroscopy appeared to be useful for QC, also for digital systems. It appears, however, that not all tests are useful or applicable for modern systems. The wording in some parts of the protocol needs to be adapted to the availability of digital systems. Performance requirements for some of the tests are not explicitly given and need to be

added. The present protocol needs the addition of a section, or an addition to each section, to state compliance with the requirements. The circular cross-sections of the Leeds Test Objects need adaptation for rectangular flat panel detector (FPD) systems.

WP2: EFFICACY AND SAFETY IN DIGITAL RADIOLOGY, DENTISTRY AND NUCLEAR MEDICINE

The objectives of this WP were to establish a consensus for the optimisation of new detectors for radiology and dentistry, and nuclear medicine, strategies for patient dose management based upon published information and acceptance, status and constancy test protocols for new detectors by building upon existing experience.

The WP consisted of two major parts, i.e. equipment performance review and consensus, and dose and optimisation approaches review and survey. Each part was split into several sub-tasks. A summary of the existing literature for equipment performance, direct digital radiography, dental radiology and nuclear medicine was sent to all SENTINEL partners. This list was updated to coincide with the release of the final report.

A survey of the QA procedures for digital radiography and for digital displays was performed on

- Digital radiography: QA test equipment, acceptance test, routine QA test[4].
- Digital display: QA test equipment, acceptance test.
- Digital display room: acceptance test, monthly QA test, annual QA test.
- Nuclear medicine.
- Direct digital radiography[5].
- Dental radiology equipment.

The previous survey of imaging parameters was updated and collated. A postal survey of techniques used for the following body-parts examined using digital radiology was undertaken:

- Skull PA, LAT,
- Thorax PA, AP, LAT,
- Cervical spine AP, LAT,
- Thoracic spine AP, LAT,
- Lumbar spine AP, LAT,
- Pelvis,
- Sacrum LAT,
- Hip, Thigh,
- Extremities I,
- Extremities II.

A comprehensive study was undertaken that involved the testing and evaluation of the Open-Source software 'Optimage' as a suitable tool for the constancy test in digital projection radiography, in accordance with the German standard DIN6868-13. The study was performed using a storage-phosphor plate system (CR) and a FPD system (DR) to test the usability of the software for both radiographic procedures, and presented during the workshop[6]. The software solution showed great acceptance in the clinical field. The central approach is flexible enough to be customised for different IT infrastructures. The development of new modules is now easy and fast due to the developed framework. The evaluation of the tests is less time-consuming than that by human observers. The included statistical functions are easy to use and are useful.

WP3: EFFICACY AND SAFETY IN INTERVENTIONAL CARDIOLOGY

The main objectives of this WP were to arrive at a consensus on image criteria for new detectors and new cardiac procedures, propose reference levels for new cardiac procedures and new detectors, collate information on the assessment of image quality and dose performance of new imaging modalities in cardiology.

This WP consisted of two major parts, one aimed at the performance of new detectors and one on the approaches to image quality, reference doses and optimisation. Each part was split into several sub-tasks for which various reports were produced. It is clear that dynamic FPD systems are increasing in the market, allowing new future applications. They offer many advantages over image intensifiers, especially due to their design and the potential of the new technology.

Cardiovascular disease, in particular coronary artery disease, remains the major cause of death, disability and hospitalisation in the industrialised world. The SENTINEL project has analysed various aspects of cardiac interventional procedure with the objective of providing an exhaustive guideline and methods aiming to optimise the use of ionising radiation in this important area of health service. The study has included the evaluation of methodologies applied for staff dosimetry and staff exposure in a sample of European installations, as well as the proposal of a methodology for dose constraints assessment. Data from several European countries established the large variability of interventional cardiology activity throughout Europe.

The cardiac SENTINEL group has developed a series of tools to assist practitioners to assess quality and optimise procedures:

(a) A set of quality criteria is useful for the assessment of the quality of coronary angiography studies. Quality criteria should be used by cardiologists and medical physicists to assess both clinical and technical quality of the studies. A scoring system and a software tool to allow the quantification of the quality level were developed.

(b) A set of reference levels for patient exposure; doses and technical properties of a sample of studies can be compared with reference levels to identify poor aspects of the radiological practice. Reference levels comprise: (1) simple dose quantities like air kerma area product, available on-line in the angiographic room and recorded in the DICOM header of images, (2) technical quantities, such as the number of images and fluoroscopy time (FT) and (3) dose rate delivered by the angiographic unit measurable in a defined geometry.

(c) Aspects of an optimised procedure; a list of criteria to help cardiologists to identify the technical aspects of an optimised procedure.

(d) A training tool for the assessment of quality of a cardiac angiography (CA) study. A software tool comprising a set of reference CA studies scored by experienced cardiologists. The cardiologist in training is guided to score these reference studies and the tool will show the comparison of the evaluation with that performed by experienced cardiologists.

(e) A list of recommendations to optimise staff exposure, together with a first proposal of dose constraints for the first operator.

Reference levels for interventional cardiac procedures were derived from a survey[7] and are presented in Table 2.

WP4: EFFICACY AND SAFETY IN IR

The objectives of this WP were the identification of examinations and practice in existing/new member states, collation and standardisation of protocols and results for patient and staff dosimetry, and achieving a consensus on image quality/dose and standardisation of high-dose radiology.

Table 2. Example of SENTINEL reference levels derived from a European survey: interventional cardiac procedures[7].

Dose or dose analogue	Procedures		
	CA[c]	PTCA[c]	EFO[c]
KAP[a] (Gy cm^2)	45	85	35
Effective dose (mSv)	8	15	6
CD at IRP[b] (mGy)	650	1,500	—
Fluoroscopy time (min)	6.5	15.5	21
Number of cine images	700	1,000	—
Entrance surface air kerma rate	Fluoroscopy low: 13 mGy min^{-1} Image acquisition: 0.10 mGy fr^{-1}		

[1]KAP is air kerma area product.
[2]CD at IRP is cumulative dose at IR reference point.
[3]CA is coronary angiography, PTCA percutanous transluminal coronary angioplasty and EFO electrophysiological procedures.

The survey demonstrated that information on IR practice is poorly known in many Member States of the European Union. Confusion exists in the classification of the procedures. As an example of surveys, one partner contributed detailed data on the IR practice in Spain (3,932 procedures/million inhabitants; 60% diagnostic and 40% therapeutic).

A consensus was obtained for the following key points:

- Dosimetric, technical and geometrical parameters allowing the auditing of patient dose and radiological procedures should be contained in the public fields of the DICOM headers.
- Dose-area product (DAP), cumulative (skin) dose, tube voltage, tube-current exposure-time product, filtration, distances [e.g. focus-to-skin distance (FSD), focus-to-image receptor distance (FID)], radiation field sizes and angulations should be available for all the acquired series of images.
- Total DAP, cumulative dose, number of images and FT should be available in all series at the end of the procedure.
- These data should also be archived together with the images of all the archived radiological events [cine, digital subtraction angiography, fluoroscopy runs, rotational etc].
- Dosimetric reports should be available in electronic format and created such as to be easily archived in standard data bases.
- The work in progress started by IEC and DICOM to standardise the structure of the dose report should be supported.
- The MPPS (Modality Performed Procedure Step) is a useful option and radiology information system should be able to receive and process this information
- Software to exploit the DICOM header information for patient dosimetry and quality control (QC) on line should be supported and promoted.

Arising from a process of consultation with all the partners, a consensus on optimisation procedures was achieved.

With regard to the standardisation of occupational studies, the following are the key points of agreement among the SENTINEL partners:

- Occupational dosimetry in IR should follow the recommendations of the International Commission on Radiological Protection (ICRP) with regard to the use of two dosemeters (over and under the lead apron).
- Occupational effective dose should be derived from the dose values of both dosemeters used.
- Additional dosimetry on the hands should also be considered in certain circumstances.

- The irregular use of the dosemeters should be considered as a possibility when occupational doses are too low or too high. Also if 'normal' values are obtained, the proper use of personal dosimetry should also be verified periodically.
- Trigger dose levels should be established to start investigation and corrective actions.
- A follow-up of the personal doses should be performed monthly and results over trigger dose levels should be discussed with the radiologists.
- Electronic dosemeters, and values of maximum dose rate, should be used as an educational tool.
- Radiation protection tools should be submitted to a periodic QC programme.
- Reports with monthly dose values should be produced at the end of the year, compared with other similar interventional suites, and analysed with the radiologists.

The development of a patient dose protocol for new detectors was mainly addressed on dynamic flat detectors attached to recently introduced IR systems, but the study also included other digital systems using image intensifiers. Possibilities to archive short series of fluoroscopy (in DICOM format) and to use some image acquisition in rotational modes (for three dimensional reconstruction) were other aspects considered. It was decided to include them in the optimisation protocols. The patient dose protocol for new detectors was obtained using a questionnaire (EXCEL forms) prepared by partner 9 in collaboration with the team of partner 5. An agreement on the four interventional procedures to be selected for the survey was obtained.

A European dose survey was performed using the questionnaire in 13 countries[8].

Conclusions were as follows.

- Large variations in the number of IR equipment and the number of IR procedures per population, in entrance dose rates.
- Large variations in DAP values, FT and number of frames.
- No clear correlation between total DAP and entrance dose rate, or between total DAP and FT.
- Preliminary reference levels that are proposed, to be used cautiously (first approximation).
- Need to improve optimisation.
- The definition and grouping of IR procedures should be improved, also taking into account for complexity of the procedure.

WP5: EFFICACY AND SAFETY IN POPULATION SCREENING/SENSITIVE GROUPS

The objectives of this WP were to obtain consensus on objective physical measures in screening techniques, and consensus and collation of dose surveys for new generation screening equipment, consensus on equipment surveys and consensus on an optimisation process for new screening equipment.

An initial questionnaire was sent to all SENTINEL partners to survey approaches to establish reference doses in paediatric radiology, to collect paediatric patient dose data and to survey how doses had been measured in these centres. A meeting was organised to discuss paediatric dose data collection. The data were processed and the results were presented during the SENTINEL workshop in Delft[9]. It was concluded that there was no generally accepted consensus on the establishment of reference doses in paediatrics. Preliminary diagnostic reference levels (DRLs) could be proposed, but there is a need for more action in this area. Data collection should focus both on centres specialised in paediatric radiology, as well as on centres with only a limited number of paediatric doses.

The survey on mean glandular dose in mammography was aimed at automatic dose data retrieval and processing. This was possible for digital mammography systems (Siemens Novation, Agfa CR, Giotto, Fuji CR). Mean glandular doses were compared with the doses from film-screen mammography[10].

A literature review and a series of practical measurements on the QA/QC of dual energy X-ray absorptiometry machines were performed. A teaching course was organised. A measurement protocol was proposed and a survey was performed on a series of systems in Ireland.

In a study on image quality in mammography, simulated microcalcifications have been used for the creation of a composite image with a known number of lesions and various shapes. Such datasets are a useful tool for observer performance studies. For the creation of a basic dataset of composite images, 420 microcalcifications with various morphology, size and contrast were inserted in 59 selected raw digital mammograms obtained with a Siemens Novation DR mammography unit. The microcalcifications were simulated into 163 regions of interest having various anatomical backgrounds. These composite images were reprocessed with the Siemens processing algorithm. Experienced radiologists were asked to locate as many simulated lesions as possible and rate them under conditions of free-search. The free-response receiver operating characteristic (FROC) study has been performed for comparison of observer performance as a function of lesion characteristics and of anatomical background. Statistical analysis of FROC data was performed by the jackknife FROC (JAFROC) 2.0 software.

A method for evaluating image processing algorithms based on microcalcifications detection has been developed. A first application of this method on radiology performance on lesion detectability showed its robustness and valid statistical approach.

Single simulated microcalcifications had to be detected. The results can serve as a first reference for future studies[11].

WP6: JUSTIFICATION, ETHICS AND EFFICACY

The main objectives of this WP were to identify the ethical issues involved in the ownership of images and their use for research purposes and surveys, to increase the penetration of professional ethical knowledge and analysis into radiological practice and to identify ethical issues in radiation protection research. General aspect of ethics and policy include dealing with public attitudes[12].

The WP on justification, ethics and efficacy consisted of two major parts, i.e. one that concentrated on ethical issues regarding new screening and special techniques in digital medical imaging, safety dilemmas and referral criteria. The other concentrated on justification studies with new screening and special techniques in digital medical imaging.

Major ethical issues were identified during the workshop[13]. These were:

- Philosophical assumptions underlying ICRP Recommendations.
- Major issues around justification.
- Medico-legal issues and non-medical exposures.
- Population screening issues.
- Issues around consent, authorisation, personal choice, self-referral etc.
- Pregnancy issues.
- Non-transparent language for discourse (e.g. quantities and units).

Concerns raised regarding justification were the following:

- Sometimes weak or lacking transparency in practice.
- Seriously underdeveloped scientifically.
- Consent, individual choice and self-referral.
- Is exemption from dose-limit always warranted?
- Whistle-blower concerns raised at length on various justification issues.

In addition, there were also some concerns, under the heading of justification, about consent/authorisation; irradiation of potentially pregnant females[14]; and criteria for selection of patients for high dose or expensive procedures.

WP7: GOOD PRACTICE, GUIDANCE AND TRAINING

The objectives of this WP were as follows:

- to establish training syllabi in radiation protection and QA for new digital detectors, IR, cardiology, mammography, bone mineral densitometry, screening and associated justification, ethical and efficacy issues
- to develop training material in radiation protection in cardiology, IR, nuclear medicine and screening
- to organise training workshops in new/candidate member states

The WP on good practice, guidance and training consisted of two major parts, i.e. training materials and a syllabus for new technology, digital radiography, cardiology and IR were produced. Training material is available from the coordination action website www.dimond3.org. Training material in the form of PowerPoint presentations may be downloaded. In addition, training syllabi and associated documentation have been produced. These may also be obtained from the coordination action website. Training material on digital radiography, interventional cardiology/IR, patient dosimetry and QC, digital mammography[15], radiation protection in medicine and bone mineral densitometry[16] are available. The training course on ethics and radiation protection has proved to be particularly successful. It is intended to publish this training material as a special issue of Radiation Protection Dosimetry.

The SENTINEL project has supported and contributed to the development of a training syllabus for medical physicists in diagnostic radiology. This syllabus is being produced by a working group of the European Federation of Medical Physics Organisations. Another meeting of this working group is planned in September. Once agreed, it is intended to publish the syllabus in the European Journal of Medical Physics. Training Meetings have been organised as part of the SENTINEL project.

CONCLUSIONS

Concerning standardisation requirements for new imaging techniques, collaboration between SENTINEL and the IEC was established. The SENTINEL toolkit circulated among the participants to perform measurements of image quality and physical parameters.

A survey of the QA procedures for digital radiography and for digital displays was performed. The previous survey of imaging parameters was updated and collated. A comprehensive study was undertaken, which involved the testing and evaluation of the Open-Source software 'Optimage' that was regarded as a suitable tool for the constancy test in digital projection radiography.

The SENTINEL project has analysed different aspects of cardiac interventional procedures with the object of providing an exhaustive guideline and methods aiming to optimise the use of ionising radiation in this field. The study has included the

evaluation of methodologies applied for staff dosimetry and staff exposure in a sample of European installations for interventional cardiology, and the proposal of a methodology for dose constraints assessment.

Concerning efficacy and safety in IR, the achievements were the identification of examinations and practice in existing/new European Member States, collation and standardisation of protocols and results for patient and staff dosimetry, and consensus on image quality/dose and standardisation of high-dose radiology.

Concerning population screening and sensitive groups, a report concerning the evaluation of dose quantities in mammography has been produced. Preliminary DRLs could be proposed for paediatric radiology. The survey on mean glandular dose in mammography was aimed at automatic dose data retrieval and processing, and performed for digital mammography systems. A literature review and a series of practical measurements on the QA/QC of DEXA machines were performed.

Major issues were identified during the workshop on ethical issues. A number of issues was raised concerning justification. In addition, there were some concerns, under the heading of justification, about consent/authorisation; irradiation of potentially pregnant females; and criteria for selection of patients for high dose or expensive procedures.

Training materials were identified and a syllabus for new technology, digital radiography, cardiology and IR was produced. Training material is available from the coordination action website www.dimond3.org.

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